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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0405]

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Certifier A. Corbin

**Agency Information Collection Activities; Submission for OMB Review;
Comment Request; Medical Device Reporting: Manufacturer Reporting,
Importer Reporting, User Facility Reporting, and Distributor Reporting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting (OMB Control Number 0910-0437)—Extension

Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i (a), (b), and (c)) requires user facilities, manufacturers, and importers of medical devices to report adverse events involving medical devices to FDA. On December 11, 1995 (60 FR 63578 at 63597), FDA issued part 803 (21 CFR part 803) that implemented section 519 of the act. The regulation was amended to conform with the changes reflected in the 1997 FDA Modernization Act.

Information from these reports will be used to evaluate risks associated with medical devices and to enable FDA to take appropriate regulatory measures to protect the public health.

Respondents to this collection of information are businesses or other for profit and non-profit organizations including user facilities, manufacturers, and importers of medical devices.

In the **Federal Register** of Tuesday, October 1, 2002 (67 FR 61638), FDA requested public comment on the proposed collection of information. FDA received one comment, but it was not directly related to the information collection.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.19	25	1	25	1	75
803.30	1,000	3	3,000	1	3,000
803.33 FDA Form 3419	1,000	1	1,000	1	1,000
803.40	50	10	500	1	500
803.50	1,500	34	51,000	1	51,000
803.55 FDA Form 3417	700	5	3,500	1	3,500

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					59,075

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
803.17	3,200	1	3,200	3.3	10,560
803.18 ²	39,000	1	39,000	1.5	58,500
Total					69,060

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Include an estimated 35,000 medical device distributors. Although they do not submit medical device reports, they must maintain records of complaints.

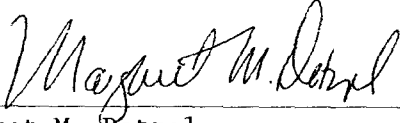
The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the medical device report (MDR) requirements as part of their internal quality control system.

Part 803 requires user facilities to report incidents where a medical device caused or contributed to a death or serious injury to the device manufacturer and to FDA (in case of death). Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur, it would be likely to cause or contribute to death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown. If the manufacturer is unknown, the importer sends the reports to FDA.

The agency has estimated that on average, 1,800 entities annually would be required to establish new procedures or revise existing procedures in order to comply with MDR provisions. For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers which are not required to revise

their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered "usual and customary" under 5 CFR 1320.3(b)(2).

Dated: 1 - 2 - 03
January 2, 2003.



Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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